PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 124.554, the Board of Pharmacy and the Prescription Monitoring Program Advisory Council give Notice of Intended Action to amend Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

The amendments were approved at the November 10, 2011, regular meeting of the Board of Pharmacy. The amendments were approved by the Prescription Monitoring Program Advisory Council by electronic communications between September 16, 2011, and October 27, 2011.

The proposed amendments define "health care professional" and "practitioner's agent" and establish criteria for the identification, authorization, and registration of a practitioner's agent to request information from the Iowa Prescription Monitoring Program (PMP). The proposed amendments clarify circumstances that may require the PMP administrator to access program information and data to resolve issues of potentially erroneous data contained in the database. The proposed amendments regarding prohibited acts and confidentiality requirements of the current rules ensure applicability of those provisions to a practitioner's agent and ensure that all individuals with access to the PMP and PMP data are aware of the criminal penalties for breach of confidentiality provisions and prohibited acts.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 3, 2012. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 124.554 and Iowa Code sections 124.553 and 124.558 as amended by 2011 Iowa Acts, Senate File 286.

The following amendments are proposed.

ITEM 1. Adopt the following **new** definitions in rule **657—37.2(124)**:

"Health care professional" means a person who, by education, training, certification, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. "Health care professional," other than a licensed prescriber or pharmacist, may include, but is not limited to, a certified pharmacy technician or a technician trainee, a nurse, or a medical assistant or supervised trainee such as a pharmacist-intern or student, a medical student, or a nursing student.

"Practitioner's agent" means a health care professional who is employed by or under the direct supervision of a health care practitioner and who is authorized by the practitioner to access PMP information as provided in subrule 37.4(1).

ITEM 2. Amend rule 657—37.4(124) as follows:

657—37.4(124) Access to database information. Prescription information submitted to the board for inclusion in the PMP database shall be privileged and strictly confidential and not subject to public or open records laws. All information contained in the PMP database, including prescription information submitted for inclusion in the PMP database and records of requests for PMP information, shall be privileged and strictly confidential and not subject to public or open records laws. The board, council,

and PMP administrator shall maintain procedures to ensure the privacy and confidentiality of patients, prescribers, dispensers, practitioners, <u>practitioners' agents</u>, and patient information collected, recorded, transmitted, and maintained in the PMP database and to ensure that program information is not disclosed to persons except as provided in this rule.

- **37.4(1)** *Prescribers and pharmacists.* A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care. A practitioner may authorize no more than three health care professionals to act as the practitioner's agents for the purpose of requesting PMP information regarding a practitioner's patients.
- a. Prior to being granted access to PMP information, a practitioner or a practitioner's agent shall submit a an individual request for registration and program access. A practitioner or a practitioner's agent with Internet access may register via a secure Web site established by the board for that purpose. A practitioner without Internet access shall submit a written registration request on a form provided by the PMP administrator. A practitioner without Internet access shall not authorize a practitioner's agent to register for or to access PMP information on behalf of the practitioner. The PMP administrator shall take reasonable steps to verify the identity of a practitioner or practitioner's agent and to verify a practitioner's credentials prior to providing a practitioner or practitioner's agent with a secure login and initial password. Each practitioner or practitioner's agent registered to access PMP information shall securely maintain and use the login and password assigned to the individual practitioner or practitioner's agent. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner or practitioner's agent, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to the practitioner's an unregistered agent. A registered practitioner's agent shall not delegate PMP information access to another individual.
- b. A practitioner or practitioner's agent with Internet access may submit a request for PMP information via a secure Web site established by the board for that purpose. The requested information shall be provided to the requesting practitioner or practitioner's agent in a format established by the board and shall be delivered via the secure Web site.
 - c. No change.
- d. A practitioner or practitioner's agent who requests and receives PMP information consistent with the requirements and intent of these rules may provide that information to another practitioner who is involved in the care of the patient who is the subject of the information. Information from the PMP database remains privileged and strictly confidential. Such disclosures among practitioners shall be consistent with these rules and federal and state laws regarding the confidentiality of patient information. The information shall be used for medical or pharmaceutical care purposes.
 - 37.4(2) to 37.4(6) No change.
- 37.4(7) PMP administrator access. Other than technical, error, and administrative function reports and information needed by PMP support staff to determine that records are received and maintained in good order or to review or resolve issues of reported or suspected erroneous data as provided in rule 657—37.7(124), any other reports concerning the information received from dispensers shall only be prepared at the direction of the board, the council, or the PMP administrator. The board and the council may compile statistical reports from PMP information for use in determining the advisability of continuing the PMP and for use in preparing required reports to the governor and the legislature. The reports shall not include information that would identify any patient, prescriber, dispenser, practitioner, practitioner's agent, or other person who is the subject of the PMP information or data.
 - ITEM 3. Amend rule 657—37.9(124) as follows:
- **657—37.9(124) Prohibited acts.** The PMP administrator shall report to the licensing board of a dispenser's or a practitioner's professional licensing board dispenser, a practitioner, or a practitioner's agent any known violation of the confidentiality provisions or the reporting requirements of the law and these rules for which the dispenser, or practitioner, or practitioner's agent is subject to disciplinary action.

37.9(1) Confidentiality. A pharmacy₂ or a pharmacist, practitioner, or practitioner's agent who knowingly fails to comply with the confidentiality provisions of the law or these rules or who delegates PMP information access to another individual, except in an emergency situation as provided in paragraph 37.4(1) "a," is subject to disciplinary action by the appropriate professional licensing board. The PMP administrator or a member of the program staff who knowingly fails to comply with the confidentiality provisions of the law or these rules is subject to disciplinary action by the board. In addition to any disciplinary action or sanctions imposed by a professional licensing board, a pharmacy, pharmacist, practitioner, practitioner's agent, PMP administrator, or member of the PMP program staff who knowingly accesses, uses, or discloses program information in violation of Iowa law or these rules is subject to criminal prosecution as provided in Iowa Code section 124.558.

37.9(2) No change.

ITEM 4. Amend **657—Chapter 37**, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 124.551, to 124.552, and 124.554 to 124.557 and sections 124.553 and 124.558 as amended by 2009 Iowa Acts, House File 122 2011 Iowa Acts, Senate File 286.